



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,617	12/17/2001	Howard Yoshihisa Ando	5953-01-CA	7789

7590 05/07/2003

Charles W Ashbrook
Warner Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

[REDACTED] EXAMINER

REYES, HECTOR M

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/07/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,617	ANDO ET AL.	
	Examiner Hector M Reyes	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 to 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 to 51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Paper Entry

Examiner acknowledges Applicant's Priority Papers filed on December 17, 2001 as paper no. 2 and PCT DO EO 903 form file on April 3, 2002 as Paper no. 3.

No Information Disclosure Statement was found in the case. However, the corresponding International Search Report for PCT IB 01/00026 was submitted along with the cited references of such report. The Examiner had been considered the said references by in the instant Office Action.

Drawings submitted with the Application are also hereby acknowledged.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 46 and 47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The use of a compound is not considered an invention from the statutory point of view. Examiner suggests the presentation of such use-claims as method-claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 43 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 43, the phrase "**a crystalline form**" is indefinite because it is not clear what is the crystalline form that will satisfy the claim-limitations.

In claim 48, the phrase "**as described herein in any of the examples**" is indefinite and vague because it makes reference to examples but lack to indicate where the said examples are properly found.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 to 45 and 49-51 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bisgaier et al, WO 9930704.

- Bisgaier discloses compositions useful in the treatment of vascular disorders and diabetes mellitus (page 1, lines 3 through 7). The said compositions comprise carboxyalkyl ether described as having the formula 1 and its salts. The most preferred composition comprises the compound described as compound III and its corresponding pharmaceutically acceptable salts (see page 2, lines 16 through 26 and page 3, lines 1 through 25). Even more specifically, the said salts are further define, identifying the calcium salt among them, see page 6, line 6 and Example 1, wherein a composition comprising the said calcium salt of compound III: 6,6'-oxybis-(dimethylhexanoic acid calcium salt said calcium salt, identified as CI-1027 is used. See also Tables 1 through 4, pages 9, 11, 13 and 15, wherein experimental data containing the said compound is disclosed. The salt's definition includes also the hydrate and solvate forms (See also page 7, lines 7-8).

Bisgaier does not disclose:

- Specific crystalline structures of derivatives of 6,6'-oxybis-(dimethylhexanoic acid calcium salt said calcium salt having the x-ray diffraction patterns or other physical characterizations or its specific preparation methods
- A method of interconversion of the said crystalline forms, pharmaceutical compositions comprising the said specific crystalline salts or methods of treating vascular diseases with the said compositions.

However, a person skilled in the art would be motivated to use conventional salt-formation methods to prepared crystalline forms of 6,6'-oxybis-(dimethylhexanoic acid calcium salt said calcium salts, including hydrates and solvates forms because the said salts are recognized by Bisgaier as preferred elements of compositions directed to the same utility as the one disclosed by the prior art. The therapeutic value of 6,6'-oxybis-(dimethylhexanoic acid calcium salt disclosed by Bisgaier and the inclusion of hydrates forms and solvates is a strong motivation to prepared specific hydrates or solvates of the same salts by conventional methods and further prepare pharmaceuticals compositions to be use in the treatment of the same conditions disclosed by the prior art. A person skilled in the art would expect the said compositions to maintain the same valuable therapeutic activity as those disclosed or suggested by Bisgaier.

CONCLUSION

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bisgaier et al, WO 96/30328, disclosing 6,6'-oxybis-(dimethylhexanoic acid and compositions disclosing the same. Such compositions are disclosed as useful in the treatment of vascular conditions. On pages 10-11 of the said reference, the preparation of salts of the said compounds is disclosed, among them, the calcium salt.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (703) 605-1153. The examiner can normally be reached on M-F 9 to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Allan Rotman can be reached on (703) 308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 or (for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Hector M. Reyes PhD JD

April 24, 2003


ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600